and selecting Process. Selecting the Process button at the bottom of the screen, once all actions have been completed, will bring up a new screen allowing you to select Sales Site Visit. If the Sales Site Visit has not been completed within three (3) days, cut and report to the DEA as suspicious all held orders in the system. Review Sales Site Visit if completed within three (3) days. Subsequent orders will be held until the three (3) day limit has passed and then similar action will be taken on all held orders (i.e. move the threshold and release the orders, as appropriate, or cut all orders).

i. Any information received from the Sales, whether proactively or in response to an inquiry, should be documented on the 074 – KYC Justification Form appropriately and loaded into Content Manager.

ii. Communicate this message to sales through use of email templates, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.

ii. If a QRA Site Visit has not been completed within the specified period of time, request a site visit within ADC by opening the customer case, checking the Site Visit box at the bottom of the Order Processing screen, and selecting Process. Selecting the Process button at the bottom of the screen, once all actions have been completed, will bring up a new screen allowing you to select QRA Site Visit and where the drug family of concern must be documented, as well. Document the QRA Site Visit request, within ADC, on the QRA Info tab of the Customer Details dashboard, specifying the drug family for which the review occurred. Until completion of the requested QRA site visit, all orders will be cut and reported to the DEA as suspicious. The requestor of a QRA Site Visit will be notified through email when the document has been loaded within Content Manager.

i. Communicate this message to sales through use of email templates, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.

b. Determine authority to set threshold by reviewing Table 2: Customer Segmentation and Review Responsibilities.[17] ADC will automatically trigger 2-person reviews in the system, when required.

b. If the all requirements are completed, set or propose threshold limit within ADC by selecting the Adjust Threshold radio button found in the Order Processing section of the customer case screen. Selecting the Process button at the bottom of the screen, once all actions have been completed, will bring up a new screen allowing you to set or propose the new threshold limit. Set or propose threshold limit based on the Threshold Change Reference found in the Tableau file. The threshold limit should be set no

[17] See Appendix 2 for Customer Segmentation and Review Policies.

higher than the Threshold Change Reference suggests, but may be set lower should it be reasonable to do so.

a. Threshold limits are aligned to the prescription volume of a customer.
b. For those customers not on either the CIM or Leader program, prescription volume is based entirely on its sales volume and the threshold will be set accordingly.
c. For those customers participating in either the CIM or Leader program, prescription volume is based on its sales volume and the CIM or Leader data. The threshold will be set taking into consideration both of these data points. Customers on these programs will be given credit for 50% of the delta between actual prescription volume and the prescription volume derived from purchases.
d. The Threshold Change Reference found in the Tableau file takes into account total prescription volume.
e. Account for AAP

7. Accrual Adjustments

Accrual adjustments should rarely occur and should only be made in the following scenarios:

a. If a customer has incorrectly entered the quantity of bottles/dosage units, the accrual total may be adjusted. Customers may directly reach out to indicate that an order entry error has occurred, but there may be times where communication with Sales is appropriate to determine if an order entry error has occurred.
b. If a customer returns part or all of a previously shipped order, within the same accrual period, the accrual total may be adjusted for that customer. Returns may be communicated by either the customer or Sales and should be confirmed with/by _____.

8. Secondary Threshold Limits

Secondary thresholds for Retail Chains will remain static and no changes will be made to the previously set limits. For a list of secondary thresholds reference Table 8: Secondary Customer Threshold Limits.[18]

9. Threshold Adjustments to Non-Top 13 Drug Families

For those drug families outside of the non-top 13 drug families, apply the logic outlined in Table 9: Non-Top 13 Drug Family Threshold Change Guidance.

[18] See Appendix 8 for Secondary Customer Threshold Limits.

APPENDIX

Appendix 1

Table 1: List of 13 Drug Families

Base Code	Description
1100	DL-AMPHETAMINE SULFATE MONOBASIC
1724	METHYLPHENIDATE HYDROCHLORIDE
2737	CLONAZEPAM
2783	ZOLPIDEM BITARTRATE(HEMI)
2882	ALRPAZOLAM
5000	CARISOPRODOL
9143	OXYCODONE HYDROCHLORIDE
9150	HYDROMORPHONE HYDROCHLORIDE
9193	HYDROCODONE BITARTRATE
9250	METHADONE HYDROCHLORIDE
9300	MORPHINE SULFATE
9652	OXYMORPHONE HYDROCHLORIDE
9801	FENTANYL CITRATE

Appendix 2

Table 2: Customer Segmentation and Review Responsibilities

	Authority to Set Limit			Information Needed			
Zone	Danni's Team	2-Person Review	LV-TAC	Sales SV	QRA SV	Objective Criteria	Subjective Criteria
A1	X	X (VP)	X	X	X	X	X
A2	X	X (VP)	X	X	X	X	X
B1	X	X (Pharmacists)		X	X	X	X
A3	X	X (Pharmacists)		X	X*	X	X
B2	X			X		X	X
B3	X			X		X	X
C1,C2,C3	X					X	X

*** Pharmacists determine whether a QRA site visit is needed.**

Appendix 3

Table 3: Objective Criteria & Score Model

Criteria	Percent Within	Floor Dosage Units	Percentage		Score Reference			
			Floor	Cap	3	4	5	12
1. Oxycodone 15,30MG Generic	Oxycodone	6,000	20%	65%	47%	56%	65%	>=65%
2. Hydrocodone 10MG Generic	Hydrocodone	8,000	40%	85%	67%	76%	85%	>=85%
3. Alprazolam 2MG	Alprazolam	5,000	15%	60%	42%	51%	60%	>=60%
4. Controlled Substances	All Rx in Dosage Qty	15,000	20%	55%	41%	48%	55%	>=55%
5. Oxycodone and Hydrocodone	Rx Scripts	*20,000	6%	13.5%	11%	12%	13.5%	>=13.5%
6. ADHD	Controlled Substances	10,000	7%	50%	33%	41%	50%	>=50%
7. Benzos	Controlled Substances	10,000	25%	65%	49%	57%	65%	>=65%
8. Opiates	All Rx in Dosage Qty	15,000	15%	42%	31%	37%	42%	>=42%

***Only criteria one through three (1-3) apply to CVS, Kroger, and Walgreens, with the exception of Walgreens Florida stores, which are subject to all eight (8) criteria.**

Appendix 4

Table 4: National Accounts Contact List

Customer Name	National Markets Sales
Balls Food Group	Brandon Wilkins/Bob Balcerek/Chris Wendel
Bashas	Yvonne Foster/Chris Wendel
BiLo	Jeff Price/Chad Schwinn/Susan Hoffman/Ron Clerico
Buehler's/Ritzman	Brandon Wilkins/Bob Balcerek/Chris Wendel
C&K Markets	Ruan McCoy/Chris Wendel
CVS	Alana Millonzi/Mollie Hills/Greg Ewing
Discount Drug Mart	Brandon Wilkins/Bob Balcerek/Ron Clerico
DZA/Hannaford/Food Lion/Harveys/Sweetbay	Brandon Wilkins/Bob Balcerek/Ron Clerico
Fruth	Jennifer Carley/Susan Hoffman/Chris Wendel

Harris Teeter	Jeff Price/Chad Schwinn/Susan Hoffman/Ron Clerico
Hi School	Ryan McCoy/Bob Balcerek/Chris Wendel
Kerr	Suzanne Livingston/Chad Schwinn/Susan Hoffman/Ron Clerico
Kmart	Alan Pinyerd/Mollie Hill/Greg Ewing
Kroger	Erin Wright/Lisa Penn/
Lewis Drug	Brandon Wilkins/Bob Balcerek/Chris Wendel
Pharmaca	Ryan McCoy/Yvonne Foster/Bob Balcerek/Chris Wendel
Price Chopper	Jennifer Carley/Jeri Wolf/Susan Hoffman/Ron Clerico
Rosauers	Ryan McCoy/Bob Balcerek/Chris Wendel
Safeway	Jennifer Carley/Bob Balcerek/Ron Clerico
Walgreens/ Duane Reade	Pam Holohan/Lisa Penn/Kraig Corwin
Weis	Suzanne Livingston/Jeri Wolf/Susan Hoffman/Ron Clerico

Appendix 5

Table 5: Customer Release Percentage

Threshold Limit	Allowable Percentage Over Threshold per Drug Family per Accrual Period	Example
0-10,000	15%	DF: 9193 TH:8,000 Accrual:7,000 Order: 2,000 Order would be released, but this rule would not apply to any subsequent orders for this drug family during the accrual period. DF 9193 TH: 8,000 Accrual 7,000 Order: 2,500

		Order would be cut, as it is outside the 15% allowable release window.
10,000-20,000	10%	DF: 1100 TH: 15,000 Accrual: 10,000 Order: 6,000 Order would be released, but this rule would not apply to any subsequent orders for this drug family during the accrual period. DF: 1100 TH: 15,000 Accrual: 10,000 Order: 7,000 Order would be cut, as it is outside the 10% allowable release window.
Above 20,000	5%	DF: 9143 TH: 32,000 Accrual: 30,000 Order: 3,500 Order would be released, but this rule would not apply to any subsequent orders for this drug family during the accrual period. DF: 9143 TH: 32,000 Accrual: 30,000 Order: 4,000 Order would be cut, as it is outside the 5% allowable release window.

Appendix 6

Table 6: Cardinal Health Distribution Position

National Chain Account	Primary Position	Secondary Position
CVS & Kroger	All Schedule 2 products are purchased direct from Cardinal Health. Cardinal Health also ships most brand products (CS and non-CS) direct to the chain warehouse. These brand products are shipped to the store from the chain warehouse.	Cardinal Health is the back-up distributor for Schedule 3, 4 & 5 products. The chain warehouse is the primary distributor for these products. Cardinal Health distributes these products when the chain warehouse is

		out of stock, does not carry the product, or the store needs delivery earlier that the weekly delivery from the chain warehouse.
Walgreens	All Schedule 2 products for Florida stores are purchased direct from Cardinal Health. Cardinal Health also ships most brand products (CS and non-CS) direct to the chain warehouse. These brand products are shipped to the store from the chain warehouse.	Cardinal Health is the secondary distributor for all controlled substance products for all stores (except for CII products for Florida stores). The Walgreens warehouse is the primary distributor for all controlled substance shipments direct to the stores.

Appendix 7

Table 7: Distribution Center Pharmacists Assignments

Distribution Center	DC#	Accrual Cycle End Date
Pharmacist – Janet Ng		
Swedesboro	43	7
Syracuse	3	7
Boston	6	14
Greensboro	26	21
St. Louis	18	28
Hudson	24	28
Pharmacist – Kimberly Anna-Soisson		
Knoxville	9	14
Jackson	10	21
Lakeland	11	28
Pharmacist- Doug Emma		
Kansas City	27	7
Wheeling	8	21

Aurora	15	21
Denver	29	28
Pharmacist – William Brady		
Auburn	37	7
Dallas	16	7
Valencia	32	21
Phoenix	19	21
Houston	28	28
Salt Lake City	35	28
Sacramento	34	14
Pharmacist – Christopher Forst		
Kinray	64	28
Ambulatory Care	97	28
All other Retail Independent		28

Appendix 8

Table 8: Secondary Customer Threshold Limits

Base Code	Description	Limit
1100	DL-AMPHETAMINE SULFATE MONOBASIC	4,000
1724	METHYLPHENIDATE HYDROCHLORIDE	4,000
2737	CLONAZEPAM	4,000
2783	ZOLPIDEM BITARTRATE(HEMI)	4,000
2882	ALRPAZOLAM	4,000
5000	CARISOPRODOL	4,000
9143	OXYCODONE HYDROCHLORIDE	7,000
9150	HYDROMORPHONE HYDROCHLORIDE	4,000
9193	HYDROCODONE BITARTRATE	4,000
9250	METHADONE HYDROCHLORIDE	4,000

9300	MORPHINE SULFATE	4,000
9652	OXYMORPHONE HYDROCHLORIDE	7,000
9801	FENTANYL CITRATE	4,000

Appendix 9

Table 9: Non-Top 13 Drug Family Threshold Change Guidance

New Threshold Limit	Requirements
0-5,000	• No need to do meaningful analysis of objective and subject criteria. • Can set threshold limit.
5,000-10,000	• Customer must pass through both objective and subjective criteria. • Can set threshold limit, but anything over 6,000 should be assigned to designated pharmacist for review, with appropriate comments included.
10,000-15,000	• Customer must pass through both objective and subjective criteria. • Proposed threshold limit must be approved by either Nick or Chris.
≥ 15,000	• Customer must pass through both objective and subjective criteria. • Proposed threshold limit must • be approved by either Todd.

QRA SOM Customer Analytics
General Work Instructions

Scope

These general guidelines are limited to Retail Independent and Retail Chain customers ordering controlled substances through the core pharmaceutical distribution business[1], as well as the thirteen drug families[2] designated as having a potentially high risk for abuse and diversion. These guidelines apply to all individuals who have the ability and/or direct responsibility for assessing and adjusting customer threshold limits for the aforementioned customers and drug families.

Effective Date

January 15, 2013

Statement

Cardinal Health's QRA department will have a standardized method to assess and adjust threshold limits utilized within the electronic monitoring system of the Suspicious Order Monitoring (SOM) program.

For purposes of these guidelines, the assessment and adjustment process is outlined from initiation to conclusion. The initiation of an assessment could result from a held order or proactive communication from the customer or sales team. The assessment could conclude with no change to a threshold limit, an increase or decrease to a threshold limit, resolution of a held order, and/or the report of a suspicious order to DEA.

The following outlines the sequence of steps and corresponding decisions that should generally occur for each type of assessment.

1. **Determine customer's class of trade:** The guidelines only apply to Retail Independent and Retail Chain customers. If the customer's class of trade is Retail Independent or Retail Chain, proceed to step 2.

    a. Class of trade can be found within ADC, indicated as Business Activity, on the Account Info tab of the Customer Details dashboard.
    b. Customers within other classes of trade are to be managed by the appropriate pharmacists as dictated by the current responsibility breakdown by DC.[3]

2. **Evaluate type of assessment:** Two distinct mechanisms may initiate the need to review a customer's threshold limit. These mechanisms include:

    a. Held order: order held by the electronic monitoring system, occurring when a customer's accrual exceeds the threshold limit. All orders held by the electronic monitoring program will appear in ADC.
    b. Proactive review: occurring when a sales representative or other party proactively communicates to QRA the potential need for threshold review. The communication could occur via email or via a phone conversation.

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[1] Core pharmaceutical distribution business includes customers serviced by the 20 forward distribution centers.
[2] See Appendix 1 for the List of 13 Drug Families.
[3] See Appendix 8 for Distribution Center Analyst/Pharmacist Assignments.

3. **Determine if assessment is warranted:** An evaluation of the set of circumstances specific to each customer is needed in order to determine if an assessment of the threshold limit is warranted. The set of circumstances reviewed should generally include, but is not limited to, the following for each type of assessment.

a. Held Orders: orders held by the electronic monitoring program will appear in ADC and require action, but not necessarily an assessment of the threshold limit. The following steps should generally occur to evaluate the held order and assist in determining if an assessment is warranted.

    a. Evaluate case within ADC, which appears on the dashboard.
    b. Identify customer by specifically reviewing the DEA #, name, location and class of trade.
    c. Determine the drug family for which the evaluation is generated by. This will be noted within ADC, indicated as Substance, on the Customer Cases tab of the Customer Details dashboard. Assess recent cases regarding the same drug family, or other drug families, to understand previous decisions and actions completed. This information can be found within ADC, indicated as Substance, on the Customer Cases tab of the Customer Details dashboard, as well. Opening a previously resolved case and reviewing the Order Processing portion of the screen will outline the actions taken for that previously held order.
    d. If the customer's class of trade is Retail Chain, determine Cardinal Health's distribution position.[4] Analysis will vary depending on whether Cardinal Health is the customer's primary wholesaler or in some other distribution position.
    e. Review customer comments found within ADC on the QRA Info tab of the Customer Details dashboard. Use these comments to determine if any new information has been included since the prior review and, if so, determine the value of this new information in your analysis of the customer.
    f. Review any new or pertinent due diligence documents which are found within ADC on the Customer Profile Tab of the Customer Details dashboard.
    g. Review the specifics of the held order to determine order size, accrual, and threshold. Accrual is shown within ADC, indicated under Volume, on the Customer Cases tab of the Customer Details dashboard. The accrual shown on the Customer Cases tab within the Customer Details screen is representative of the accrual at the time the order was held, including the held order. The accrual shown on the Order Processing screen is inclusive of all shipped product, all product to be shipped and the quantities associated with any unresolved orders held for review.
    h. Define Customer Zone within Tableau file, to determine the necessary requirements for customer analysis and threshold adjustment which can be found in Table 2: Customer Segmentation and Review Responsibilities.[5]

b. Proactive Communication:
    a. Evaluate information provided by customer or sales and determine if additional details regarding the situation are needed. If so, reach back out through the appropriate sales contact to collect this information.

[4] See Appendix 6 for Cardinal Health Distribution Position.
[5] See Appendix 2 for Customer Segmentation and Review Responsibilities.

b. Create a manual case within ADC if sufficient information is provided by customer or sales by selecting Customer Search at the top of QRA Dashboard, typing in the customer's DEA #, displaying the customer record, selecting View Customer, then selecting the Customer Cases tab on the Customer Details dashboard, and selecting Create Manual Case in the upper right corner. Follow the process for Objective and Empirical review. Instances where manual case creation is necessary may include, but is not limited to:
    i. The customer communicates that a pharmacy nearby is closing and it expects the need to increase its purchases by 15%. This 15% increase in purchases would cause threshold events, based on its current threshold for that drug family. The customer passes through objective criteria and empirical analysis.
    ii. The customer communicates that a recent theft/loss has occurred and this has been confirmed through the documentation of a DEA form 106 – Theft/Loss Report. Due to this confirmed theft/loss, an increase to one or more threshold limits for the month may be necessary.
    iii. The customer communicates that it will be or has started servicing new hospice or long-term care facilities, requiring a pharmacist's review of available information.

An assessment is always required to increase a customer's threshold limit.

c. Assessment of the customer and its threshold is warranted in the following scenarios (non-exhaustive list):
    i. The customer has not previously been assessed using the revised threshold limit methodology and guidelines. Customers who have previously been assessed will have documented comments from QRA personnel on the QRA Info tab of the Customer Details dashboard.
    ii. Review of due diligence documents shows new information has been made available since the most previous review. New information could include a new site visit or change in business model as noted by QRA personnel. Due diligence files will be listed in order from newest to oldest in the Customer-related Documents section on the Customer Profile tab of the Customer Details dashboard.
    iii. A customer's orders significantly differ from previous orders (i.e. spike or increase in orders). Customer Zone will be documented in the customer comments on the QRA Info tab of the Customer Details dashboard, when appropriate. Comparing the previously documented zone to the Customer Zone within the Tableau file will help determine if a change has occurred.

d. Assessment of the customer and its threshold is not warranted in the following scenarios[6] (non-exhaustive list):

    i. Review of due diligence documents indicates that no new information or due diligence has been made available since the most previous review. Due diligence files will be listed in order from newest to oldest in the

[6] For held orders, this may result in the order being cut and reported as suspicious to the DEA.

Customer-related Documents section on the Customer Profile tab of the Customer Details dashboard.

ii. Notations have been made in the customer comments section to indicate that shipments above threshold limit are not to occur.

iii. The customer has been terminated from purchasing controlled substance products from Cardinal Health. A customer who has been suspended from purchasing controlled substance products from Cardinal Health will have a threshold of one (1). This will be noted within ADC and can be found on the Customer Cases tab within the Customer Details dashboard under the Volume heading or by opening the customer case and reviewing the threshold listed on the Order Processing section of the screen. This will also be noted within ADC as Current Status on the Customer Block/Reinstate tab of the Customer Details dashboard.

4. **Objective Assessment:** When it is determined that a customer and a threshold limit warrant additional assessment, the customer's objective criteria should be assessed. The objective criteria include a standardized set of metrics used to assess the customer's overall profile. The review of objective criteria generally includes the following steps:

a. Review customer specific Tableau file, specifically evaluating the following components:
    a. Customer Zone of drug family or families triggering assessment.
    b. Review trend of drug family or families triggering assessment, specifically evaluating spikes and underlying strengths.
    c. Review objective criteria metrics, specifically evaluating the total score[7]. If a customer is part of the CIM or Profit Leader program, reference the score generated from that data. If the customer is not part of the CIM and Profit Leader program, reference the score generated from purchase data to determine if the customer passes or fails. The final score should be documented within ADC, when appropriate, as a customer comment on the QRA Info tab of the Customer Details dashboard. Note: CVS and Kroger are subject to a limited number of Objective Criteria (Oxy 15/30MG Gen, Hydro 10MG Gen, Alprazolam 2MG) due to their distribution position with Cardinal Health.
        i. When a customer's total score is greater than twelve (>12) and, after empirical review, there is no justification for threshold adjustment:
            a. When appropriate, within the Customer Comments section of ADC, document the score, credited monthly prescription count, drug family and Customer Zone.
            b. Within ADC, cut the order by selecting the Cut Order radio button found in the Order Processing section of the customer case screen.
            c. Within ADC, adjust the accrual for the customer by selection the Adjust Accrual radio button found in the Order Processing section of the customer case screen.

[7] See Appendix 3 for Objective Criteria and Score Model.

d. Within ADC, report the order as suspicious by selecting the Report to DEA radio button found in the Order Processing section of the customer case screen.
e. Communicate the decision and the reasoning to the appropriate sales personnel. Email templates for communication can be which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.
    i. For Retail Independent customers, the communication should be sent to the PBC responsible for the customer. The sales rep can be identified within ADC on the Sales Rep tab of the Customer Details dashboard.
    ii. For Retail Chain customers, the communication should be sent to the primary Cardinal Health sales contact responsible for the National Account. A complete list of contacts for each National Account can be identified in Table 4: National Accounts Contact List[8] and a complete list of banners associated with each national account can be found in Table 7: Chain Banners[9].
f. Customers may receive a specified percentage of dosage units above their thresholds, once an accrual per drug family. The percentage allotted is dependent upon the size of the customer's threshold limit and can be found in Table 5: Customer Release Percentage.[10] If this release percentage is utilized during an accrual period, it should be noted as follows: score, credited monthly prescription count, drug family, Customer Zone, and appropriate comment within the Customer Comments section of ADC (ex. oxycodone - release used for accrual period).
    a. Releases outside specified percentages may occur due to patient-specific needs after consultation and approval by QRA leadership.

ii. When a customer's total score is less than twelve (<12):
    a. When appropriate, within the Customer Comments section of ADC, document score, credited monthly prescription count, drug family and Customer Zone.
    b. Proceed to the empirical review in Step 5.

5. **Empirical Assessment:** When it is determined that a customer passes the objective review, an empirical assessment of the customer and available information to assess the reasonableness of the information and underlying basis for the threshold limit increase should occur. The review of empirical criteria generally includes, but is not limited to, the following steps:

[8] See Appendix 4 for National Accounts Contact List.
[9] See Appendix 7 for Chain Banners List.
[10] See Appendix 5 for Customer Release Percentage.

a. Evaluate the order and historical order trend by reviewing customer's historical order pattern within the Tableau file. Distribution and corresponding dosage unit quantity volume may be reasonable for the following reasons:
    I. Historical trend demonstrates gradual growth in the drug family over the last three (3) months.
    II. Historical trend demonstrates that the customer has not had any unjustified or unreasonable spikes in the purchase volume during the last six (6) months.
    III. The historical trend demonstrates that a shift in product purchasing/usage is evident. For example, a customer has begun purchasing less hydrocodone and has shifted these purchases to oxycodone, based on prescribing patterns or product availability.

b. Evaluate due diligence information by reviewing any information that has been made available within the last twelve (12) months. Review of any due diligence information outside of the twelve (12) month window is discretionary. Be sure to check the date the document was *created* in order to determine its relevance in the analysis process.
c. If order pattern has significantly changed from historical order pattern and an unjustified or unreasonable spike is evident, communicate with sales team to collect necessary information to support the underlying change in ordering. Acceptable responses to support this type of change include, but are not limited to:
        i. Business model changes, for example:\
            a. A pharmacy nearby has closed and the customer will be picking up the demand.
                i. In instances where sales proactively communicates this type of information, ask for information regarding the pharmacy's anticipated bump in purchases. If the customer responds with 10%, review historical purchases to determine whether the additional 10% in purchases will result in held orders. If so, and the customer has passed the objective criteria and empirical analysis, set or propose the appropriate new threshold limit. If the increase would cause the customer to change Customer Zone, follow Customer Segmentation and Review Responsibilities[11] table to understand necessary steps required for adjustment.
                ii. In instances where sales does not proactively communicate this type of information and, as a result, the customer is experiencing threshold events, determine what additional information may be needed to review. Consult with appropriate sales personnel understand any changes within the business model that may be driving the increased purchasing.
            b. The customer will now be servicing new hospice, long-term care, legitimate pain management, nursing home, or other business model. In these instances, consult with a pharmacist, when

[11] See Appendix 2 for Customer Segmentation and Review Responsibilities

appropriate, sharing pertinent information, so that the pharmacist can clinically review the held order and threshold limit.

b. Historical trend for the drug family, which can be found within the Tableau file in the Monthly Drug Family Distribution by Strength section. This may also be found within ADC by selecting the appropriate drug family listed next to Qty Shipped This Month (Dosage Units) found above the Order Processing section of the customer case screen. Situations where increased volume may be reasonable (non-exhaustive list):
    i. Trend shows gradual growth over the last three (3) months.
    ii. Trend shows customer has not had unjustified or unreasonable spikes in purchase volume during the last six (6) months.
c. Distribution position, for CVS and Kroger, which can be determined by reviewing Cardinal Health Distribution Position.[12]
d. On-site investigation reports
    a. When available, on-site investigation reports should be reviewed. The review of the report should determine if red-flags were identified during the visit. Within the Investigation Final Report, specifically pay close attention to:
        i. Those questions with Yes/No answers highlighted in red and the accompanying explanations;
        ii. Section 2. Dispensing Information, specifically noting total prescription count and percentage of cash information;
        iii. Section 4. Supplier Info, specifically noting Cardinal Health's wholesaler position;
        iv. Section 5. Due Diligence, specifically noting the investigator's observations.
    b. Full-site visit reports, conducted by an investigator, can be found within ADC or Content Manager under the naming convention 110 – Investigation Final Report.
    c. Customer call survey, conducted by an investigator, can be found within ADC or Content Manager under the naming convention 062 – Customer Update Questionnaire (Call).
    d. Surveillance site visits, conducted by an investigator, can be found within ADC or Content Manager under the naming convention 102 – Site Visit.
    e. Sales site visit reports, conducted by a PBC, can be found within WinWatcher on the Regulatory tab under "Know Your Customer – Site Survey Detail."
e. Affiliations (prescriber specialties)
    a. If available, review specialty information captured within due diligence documents.
f. If within five (5) business days, no response has been received from sales, the order is cut and reported to the DEA as suspicious and the accrual is adjusted. This can be accomplished within ADC for the specific Customer Case by selecting the Cut, Adjust Accrual and Report to DEA radio buttons, and then selecting Process, under the Order Processing portion of the screen.

[12] See Appendix 6 for Cardinal Health Distribution Position.

6. **Eligibility for threshold limit increase:** If all objective and empirical criteria are satisfactory and a customer is eligible for threshold limit increase, the following steps should generally be completed to determine the appropriate threshold limit. Instances outside of these general guidelines require approval at the Vice-President level or above.

a. Determine if a Sales Site Visit, Surveillance Site Visit or QRA Site Visit is required by reviewing Table 2: Customer Segmentation and Review Responsibilities.[13] If a Sales Site Visit is required, it must have been completed within the last 90 days. If a Surveillance Site Visit is required, it must have been requested or completed within the last 12 months. If a QRA Site Visit is required, it must have been completed within the last 12 months.

i. If a Sales Site Visit is required and has not been completed within the specified period of time, request a site visit within ADC by selecting the QRA Info tab and then selecting "Request Site Visit" at the bottom of the screen. Find "For Sales – Requested by QRA Analyst" in the drop down and enter appropriate comment. Finally, select "Request Site Visit" to initiate request. If the Sales Site Visit has not been completed after five (5) business days, take appropriate action on all orders above threshold currently held within the electronic monitoring system. If the Sales Site Visit is completed within five (5) business days, review customer information and appropriately set or propose new threshold limit.

a. Any information received from the sales, determined by QRA personnel to be pertinent to understanding a customer's business model, whether proactively or in response to an inquiry, should be documented on the 074 – KYC Justification Form appropriately and loaded into Content Manager under the correct naming convention (DEA #-074-BU-6 digit date).

b. Communicate relevant information to sales through use of email templates, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.

ii. If a Surveillance Site Visit is required and has not been completed or requested within the specified period of time, request a surveillance site visit within ADC by selecting the QRA Info tab and then selecting "Request Site Visit" at the bottom of the screen. Find "For QRA – Requested by QRA Analyst" in the drop down and enter "Routine QRA Surveillance visit." Finally, select "Request Site Visit" to initiate request. The threshold limit may be adjusted, if appropriate, prior to the completion of visit.

iii. If a QRA Site Visit is required and has not been completed within the specified period of time, request a site visit within ADC by selecting the QRA Info tab and then selecting "Request Site Visit" at the bottom of the screen. Find "For QRA – Requested by QRA Analyst" in the drop down and enter appropriate comment. Finally, select "Request Site Visit" to initiate request. Until completion of the requested QRA site visit, all orders outside of the release guidelines should be cut and reported to

[13] See Appendix 2 for Customer Segmentation and Review Responsibilities.

the DEA as suspicious and the accrual adjusted. The requestor of a QRA Site Visit will be notified through email when the document has been loaded within Content Manager.

iv. For Retail Chain customers, the requirements for Sales Site Visits, Surveillance Site Visits and QRA Site Visits vary slightly from Retail Independent. For these customers, the review should be conducted as following:

a. Sales Site Visits
    a. If the site visit request is for any drug family other than oxycodone and hydrocodone, the sales site visit does not have to be completed at the time of the threshold adjustment, but must be requested at the time the threshold adjustment is set or proposed.
    b. If the site visit is for oxycodone or hydrocodone, the sales site visit must be completed prior to setting or proposing a threshold adjustment. Request the sales site visit within ADC and ensure its completion within WinWatcher, prior to setting or proposing a threshold adjustment.

b. Surveillance Site Visit
    a. If a surveillance site visit is required by Table 2: Customer Segmentation and Review Responsibilities[14], this need not be completed prior to setting or proposing a threshold adjustment, but should be requested for completion if one has not been completed or requested in the last 12 months.

c. QRA Site Visits
    a. If a site visit is required by Table 2: Customer Segmentation and Review Responsibilities[15], this must be completed prior to setting or proposing a threshold adjustment.

b. Determine authority to set threshold by reviewing Table 2: Customer Segmentation and Review Responsibilities.[16] ADC will automatically trigger 2-person reviews in the system, when required.

b. If all requirements are completed, set or propose a new threshold limit within ADC by selecting the Adjust Threshold radio button found in the Order Processing section of the customer case screen. Selecting the Process button at the bottom of the screen, once all actions have been completed, will bring up a new screen allowing you to set or propose the new threshold limit.
    a. Threshold limits are aligned to the prescription volume of a customer.
    b. For those customers not on either the CIM or Profit Leader program, prescription volume is based entirely on its sales volume and the threshold will be set accordingly.

[14] See Appendix 2 for Customer Segmentation and Review Responsibilities.
[15] See Appendix 2 for Customer Segmentation and Review Responsibilities.
[16] See Appendix 2 for Customer Segmentation and Review Responsibilities.

c. For those customers participating in either the CIM or Profit Leader program, prescription volume is based on its sales volume and the CIM or Profit Leader data. The threshold will be set taking into consideration both of these data points. Customers on these programs will be given credit for 50% of the delta between the data feed prescription volume and the prescription volume derived from purchases.

7. LV-TAC Set Threshold Limits

If a customer's threshold limit has been recommended and agreed upon by LV-TAC, this will be indicated with the ending digit of nine (9).

8. Theft/Loss

In the event that sales or a customer reports a theft/loss of controlled substances, confirm the receipt of the DEA form 106, which indicates exactly what products were a part of the theft/loss, and adjust thresholds as appropriate to allow for the replenishment of these items. In these instances, the site visit and LV-TAC approval needs outlined in Table 2: Customer Segmentation and Review Responsibilities, are not required. Adjust threshold back down to prior level upon accrual reset for the customer. Attach DEA form 106 form to a completed 074 form and load into Content Manager.

9. Returns

In order to receive an adjustment to accrual for returns, the items that have been returned must have been purchased within the last three months. If it can be confirmed that the items returned were purchased within the appropriate timeframe, adjust the threshold appropriately to allow for purchases from the same drug family to make up for the returned items, when appropriate. For example, if a customer has an alprazolam threshold of 10,000 and it has purchased and returned 2,000 dosage units of alprazolam product within the appropriate timeframe; adjust the threshold to 12,000 for the remainder of the accrual period, if appropriate based on purchase history. Upon reset of the accrual, return threshold limit to previous level of 10,000.

10. Threshold Adjustments to Non-Top 13 Drug Families

For those drug families outside of the non-top 13 drug families, apply the logic outlined in Table 8: Non-Top 13 Drug Family Threshold Change Guidance.[17]

[17] See Appendix 9 for Non-Top 13 Drug Family Threshold Change Guidance.

APPENDIX

Appendix 1

Table 1: List of 13 Drug Families

Base Code	Description
1100	DL-AMPHETAMINE SULFATE MONOBASIC
1724	METHYLPHENIDATE HYDROCHLORIDE
2737	CLONAZEPAM
2783	ZOLPIDEM BITARTRATE(HEMI)
2882	ALRPAZOLAM
5000	CARISOPRODOL
9143	OXYCODONE HYDROCHLORIDE
9150	HYDROMORPHONE HYDROCHLORIDE
9193	HYDROCODONE BITARTRATE
9250	METHADONE HYDROCHLORIDE
9300	MORPHINE SULFATE
9652	OXYMORPHONE HYDROCHLORIDE
9801	FENTANYL CITRATE

Appendix 2

Table 2: Customer Segmentation and Review Responsibilities

Zone	Authority to Set Limit			Information Needed			
	Customer Analytics	2-Person Review	LV-TAC	Sales SV	QRA SV	Objective Criteria	Subjective Criteria
A1	X	X (VP)	X	X	X*	X	X
A2	X	X (VP)	X	X	X*	X	X
B1	X	X (Pharmacists)		X	X*	X	X
A3	X	X (Pharmacists)		X	X* **	X	X
B2	X			X		X	X
B3	X			X		X	X
C1,C2,C3	X					X	X

*** For Kroger and CVS chain pharmacies, request the completion of a Surveillance Site Visit if one has not been completed or requested within the last 12 months.**
**** Pharmacists determine whether a QRA site visit is needed.**

Appendix 3

Table 3: Objective Criteria & Score Model

[LINK Excel.Sheet.8 "C:\\Users\\yingrui.liuolesiuk\\Desktop\\Project FY13 Forward\\Project_FY2013\\Threshold\\Set_New_Thresholds\\Finalized Projects 13 Drug Families\\Objective Criteria\\Summary\\Summary_Tables.xlsx!Objective Criteria!R2C2:R11C10" "" \a \p * MERGEFORMAT]

***Only criteria one through three (1-3) apply to CVS and Kroger.**

Appendix 4

Table 4: National Accounts Contact List

Customer	Sales Lead	Director	Manager	Sr. Specialist
CVS	Paul Farley	Ashlee Hamski	Alana Millonzi	Jason Gawlik
KMart	Greg Ewing	Ashlee Hamski	Alan Pinyerd	Sue Livingston
Fred's of Tenn / Reeves-Sain/Entrust Rx	Andy Grant	Susan Hoffman	Leslie Arend	Nate Blankemeyer
Hi-School	Chris Wendel	Susan Hoffman	Ryan McCoy	George Speidel
Discount Drug Mart and Gentry Health	Andy Grant	Susan Hoffman	Leslie Arend	Sue Livingston

Fruth Pharmacies	Chris Wendel	Susan Hoffman	Leslie Arend	George Speidel
Pharmaca	Chris Wendel	Susan Hoffman	Ryan McCoy	Sue Livingston
Rosauers	Chris Wendel	Susan Hoffman	Ryan McCoy	Bob Goetzman
Price Chopper	Andy Grant	Susan Hoffman	Leslie Arend	Bob Goetzman
Weis Markets	Andy Grant	Susan Hoffman	N/A	N/A
Kroger	Greg Ewing	Theresa Shuster	Erin Wright	Nate Blankemeyer
DZA	Andy Grant	Theresa Shuster	Stacey Waweru	George Speidel
Lewis Drug	Chris Wendel	Theresa Shuster	Stacey Waweru	Bob Goetzman
Ritzman Pharmacies	Chris Wendel	Theresa Shuster	Stacey Waweru	Sue Livingston
Balls Food	Chris Wendel	Theresa Shuster	Stacey Waweru	Sue Livingston
Drug Emporium	Chris Wendel	Theresa Shuster	Erin Wright	Sue Livingston

Appendix 5

Table 5: Customer Release Percentage

Threshold Limit	Allowable Percentage Over Threshold per Drug Family per Accrual Period	Example
0-9,999	15%	DF: 9193 TH:8,000 Accrual:7,000 Order: 2,000 Order would be released, but this rule would not apply to any subsequent orders for this drug family during the accrual period. DF 9193 TH: 8,000

		Accrual 7,000 Order: 2,500 Order would be cut, as it is outside the 15% allowable release window.
10,000-19,999	10%	DF: 1100 TH: 15,000 Accrual: 10,000 Order: 6,000 Order would be released, but this rule would not apply to any subsequent orders for this drug family during the accrual period. DF: 1100 TH: 15,000 Accrual: 10,000 Order: 7,000 Order would be cut, as it is outside the 10% allowable release window.
20,000 +	5%	DF: 9143 TH: 32,000 Accrual: 30,000 Order: 3,500 Order would be released, but this rule would not apply to any subsequent orders for this drug family during the accrual period. DF: 9143 TH: 32,000 Accrual: 30,000 Order: 4,000 Order would be cut, as it is outside the 5% allowable release window.

Appendix 6

Table 6: Cardinal Health Distribution Position

Accounts name	Primary Source for Schedule II	Source for other Schedule Drugs	Primary Source for all other Rx Drugs
Fred's of Tenn / Reeves-Sain/Entrust Rx	All Schedule 2 products are purchased direct from Cardinal Health.	Cardinal Health	Cardinal Health
Fruth Pharmacies	Cardinal Health	Cardinal Health	Cardinal Health

Discount Drug Mart and Gentry Health	Cardinal Health.	Cardinal Health is the back-up distributor for Schedule 3, 4 & 5 products. The chain warehouse is the primary distributor for these products. Cardinal Health distributes these products when the chain warehouse is out of stock, does not carry the product, or the store needs delivery earlier than the delivery from the chain warehouse.	Self-wareouses 1,800 generic products.
Ritzman Pharmacies	Cardinal Health	Cardinal Health	Cardinal Health
Drug Emporium	Cardinal Health	Cardinal Health	Cardinal Health
Safeway-Albertsons	Cardinal Health	Cardinal Health	Cardinal Health
DZA	Cardinal Health	Cardinal Health	Self-warehouses non-controlled product.
Hi-School	Do not stock CII's in their own warehouse.	Class Code 20 stores (21- Corporate stores) primary supplier is Cardinal Health. Member independent stores (appox 77 stores) can purchase Cardinal through a secondary source such as Anda.	Northwest Generics. Hi-School has its own brand of OTC items, as well.
Lewis Drug	Cardinal Health	Cardinal Health	Cardinal Health
Rosauers	Carainal Health	Cardinal Health	Cardinal Health
Balls Food	Cardinal Health	Cardinal Health	Cardinal Health
Pharmaca	Cardinal Health	Cardinal Health	Cardinal Health
KMart	Cardinal Health	Cardinal Health	Cardinal Health
CVS	All Schedule 2 products are purchased direct from Cardinal Health. Cardinal Health also ships most brand products (CS and non-CS) direct to the chain warehouse. These brand products are shipped to the store from the chain warehouse.	Cardinal Health is the back-up distributor for Schedule 3, 4 & 5 products. The chain warehouse is the primary distributor for these products. Cardinal Health distributes these products when the chain warehouse is out of stock, does not carry the product, or the store needs delivery earlier that the weekly delivery from the chain warehouse.	Cardinal Health is back-up distributor for non-controlled products.
Kroger	All Schedule 2 products are purchased direct from Cardinal Health. Cardinal Health also ships most brand products (CS and non-CS) direct to the chain warehouse. These brand products are shipped to the store from the chain warehouse.	Cardinal Health is the back-up distributor for Schedule 3, 4 & 5 products. The chain warehouse is the primary distributor for these products. Cardinal Health distributes these products when the chain warehouse is out of stock, does not carry the product, or the store needs delivery earlier that the weekly delivery from the chain warehouse.	Cardinal Health is back-up distributor for non-controlled products.

Appendix 7

Table 7: Chain Banners List

Chain Affiliation	Banner Name
CVS	Hook-SupeRx, L.L.C.
CVS	Longs Drug Stores California, L.L.C.
Kroger	Jay-C
Kroger	Dillon's

Kroger	Baker's
Kroger	Kroger Kwik
Kroger	Gerbes
Kroger	Fry's
Kroger	King Soopers
Kroger	City Market
Kroger	Fred Meyer
Kroger	QFC
Kroger	Ralphs
Kroger	Smith's
Kroger	Harris Teeter
Kroger	Payless
Kroger	Scott's
Kroger	Food 4 Less
Kroger	PPS (Postal Prescription Service)
Kroger	JR
Safeway	Vons
Safeway	Dominicks
Safeway	Randalls
Safeway	Tom Thumb
Safeway	Pavillions
Delhaize (DZA)	Hannaford
Delhaize (DZA)	Food Lion
Delhaize (DZA)	Martin's Food

Appendix 8

Table 8: Distribution Center Analyst/Pharmacist Assignments

Distribution Center	Distribution Center Number	Specialist	Non-Retail/Non-Chain Specialist (Pharmacist)	Region	Accrual Reset Cycle
Swedesboro	43	Nikki Edwards	Doug Emma	1	8
Syracuse	3	Nikki Edwards	Doug Emma	1	8
Boston	6	Nikki Edwards	Doug Emma	1	15
Greensboro	26	Nikki Edwards	Doug Emma	1	22
St. Louis	18	Nikki Edwards	Doug Emma	1	1
Hudson	24	Nikki Edwards	Doug Emma	1	1
Dallas	16	Nikki Edwards	Bill Brady	1	8
Kansas City	27	Laura Shinkle	Doug Emma	2	8
Jackson	10	Laura Shinkle	Bill Brady	2	22
Lakeland	11	Laura Shinkle	Bill Brady	2	1
Auburn	37	Laura Shinkle	Bill Brady	2	8
Knoxville	9	Dominic Palumbo	Bill Brady	3	15
Wheeling	8	Dominic Palumbo	Doug Emma	3	22
Aurora	15	Dominic Palumbo	Doug Emma	3	22
Denver	29	Dominic Palumbo	Doug Emma	3	1
Valencia	32	Becki Durra	Bill Brady	4	22
Phoenix	19	Becki Durra	Bill Brady	4	22
Houston	28	Becki Durra	Bill Brady	4	1
Salt Lake City	35	Becki Durra	Bill Brady	4	1
Sacramento	34	Becki Durra	Bill Brady	4	15
Kinray	64	Meredith Deitrick	Bill Brady	Kinray	1
ParMed	94	Janet Ng		East	1
Brokerage	BRK	Janet Ng		East	1
PharmPak	98	Janet Ng		East	1
SPD-LaVergne	80	Janet Ng		East	1
SPD-Reno	90	Janet Ng		East	1
Ambulatory Care	97	Chris Forst		6	1
SPS-Reno	300	Chris Forst		East	1
SPS-LaVergne	100	Chris Forst		East	1
NLC	99	Chris Forst		East	1
Puerto Rico	66	Liz Sanchez Marcano	Liz Sanchez Marcano	5	1

Appendix 9

Table 9: Non-Top 13 Drug Family Threshold Change Guidance

Category	Authority to Set Limit Danni's Team	2-Person Review (Pharmacist)	2-Person Review (VP)
Tier 1	<=2k	Between 2k and 10k	Above 10k
Tier 2	<=5k	Between 5k and 15k	Above 15k
Tier 3	<=5k	Between 5k and 25k	Above 25k
Tier 4	<=15k	Between 15k and 25k	Above 25k
Pseudoephedrine	=<15k	Between 15k, and 25k or 45k*	Above 25k or 45k

*Low volume season (March-August): 25k
*High volume season (September-February): 45k

QRA INVESTIGATIONS

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide guidance to Cardinal Health employees involved in investigating Cardinal Health customers for the potential risk of diversion of controlled substances, listed chemicals and/or monitored drugs.

The purpose of this SOP is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, to meet the obligations set forth in the Administrative Memorandum of Agreement (MOA) effective May 14, 2012, and to meet or exceed the Drug Enforcement Administration's (DEA) expectations of distributors that have been communicated to Cardinal Health through informal, non-binding communications.

The purpose of this SOP is also to define additional responsibilities performed by the Anti-Diversion Team Investigative Group.

2.0 SCOPE

This SOP applies when Cardinal Health Corporate Quality and Regulatory Affairs (QRA) determines that an investigation of a DEA-registered customer is necessary to meet the objectives outlined in §1.0 above. The SOP apply to all retail pharmacies, including chain pharmacies.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx"]	Detecting and Reporting Suspicious Orders and Responding To Threshold Events
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"]	QRA Investigation Form
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form3.docx"]	Decision Memo
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]	Large Volume – Tactical and Analytical Committee Review Process

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/DR-P007.docx"]	Good Documentation Practices
(800) 926-0834	Cardinal Health Ethics and Compliance Hotline

4.0 RESPONSIBILITIES

The designated Cardinal Health employee(s) responsible for Suspicious Order Monitoring (SOM) have the primary responsibility for compliance to this SOP.

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC) System	Case management system used to facilitate the evaluation and assessment of threshold events, which are orders for controlled substance products held by the Suspicious Order Monitoring (SOM) electronic monitoring program. The case management system also allows members of Quality and Regulatory Affairs to reference customer specific information, as well as make adjustments to threshold limits and restrict customers from purchasing controlled substances.
Case	An investigation of a customer conducted after a threshold event or after Cardinal Health learns other information that warrants an on-site investigation to obtain the information necessary to assess the customer's potential risk for diversion.
Customer	Any retail pharmacy customer regulated by and properly licensed in good standing with the Drug Enforcement Adinistration and any other agencies as required by state or federal law for the purchase of regulated drugs.
Customer Category	The category to which the customer belongs based on three (3) month average monthly volume for the drug family leading to the customer site-visit request as set by the Vice-President
Distrack	Cardinal Health warehouse management system that is utilized by Pharmaceutical Distribution. This is an automated management system and includes information such as customer names, inventory, orders, shipments, threshold, etc.
Investigator	An individual authorized by Cardinal Health to conduct on-site investigations of customers at the direction of the Director. These individuals include Quality and Regulatory Affairs employees, designated Cardinal Health employees, or authorized outside contractors.
Regulated Drug	Controlled substances, List 1 and 2 Chemicals, and other drugs required to be monitored by individual states.

Suspicious Order A customer's order for a:

- Controlled substance which is of an unusual size, deviates substantially from a normal pattern, or is ordered with unusual frequency;
- List 1 or 2 Chemical which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the listed chemical will be used in violation of the federal Controlled Substances Act; or
- Drug required to be monitored by an individual state which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the drug may be used in violation of state law.

Tableau Software tool that allows user to view analytical data and visualizations (charts/graphs) in an interactive format.

Threshold The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event An order for a regulated drug which exceeds the threshold set for a specific licensed customer.

6.0 PROCEDURE

6.1 Receipt and Assignment of Cases

6.1.1 Receipt of Cases

6.1.1.1 Site-visit cases are received from four (4) sources:

a. From QRA Pharmacists who request site-visits to pharmacies based on the totality of circumstances for suspicious orders (or order lines) according to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx"].

b. From QRA-Analytics team members who request a site-visit based on a review of the store's objective criteria according to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"].

c. From the Large Volume Tactical and Analytical Committee (LV-TAC) that selects certain customers considered to present a higher risk of diversion based on criteria like volume of controlled substance purchases, growth in controlled substance purchases and others factors according to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"].

d. From requests from other Cardinal Health business units or via the Cardinal Health Ethics and Compliance Hotline (800) 926-0834.

6.1.2 Assignment of Cases

6.1.2.1 All site-visit request are entered through ADC. The Director then assigns cases to QRA investigators and/or external contractors.

6.1.2.2 QRA investigators and/or external contractors must schedule and complete the site-visits within a reasonable period of time and submit the completed report ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"]) within a reasonable period of time after the visit. The Director must determine what constitutes a reasonable amount of time based on variable factors such as visit priority, investigator workload, and geographical locations.

6.1.2.3 The party responsible for requesting the investigation generally request the type of investigation to occur, which is included in the ADC request. However the Director assigns the type of investigation to the investigator that must occur based on a review of circumstances that underlie the reason for the investigation request. One of three (3) types of investigations may be assigned:

a. **On-site investigation**: Investigator conducts an announced investigation at the customer's DEA registered location. Investigator interviews the Pharmacist In Charge (PIC) and/or other employees as necessary.
b. **Surveillance Visit**: Unannounced, the investigator physically travels to and conducts surveillance upon the customer's DEA registered location for visible signs of diversion.
c. **Customer Call Survey**: The investigator schedules a phone interview with the PIC to review/confirm items relevant to the customer's business practice regarding controlled substances.

6.1.2.4 All investigations must be documented on [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"]. All reports must be submitted to the Director for review. The Director reviews all investigation reports, completes the corporate review portion of the document and ensures upload to ADC. Upon inclusion in ADC, the report is available for review by the requester of the site-visit, as well as other QRA team members.

6.2 QRA Investigator (or Contractor), Site-Visit Process

6.2.1 Background Preparation

6.2.1.1 Upon assignment of an investigation, the investigator contacts the relevant Pharmacy Business Consultant (PBC) or Sales Manager to inform of the site-visit and arrange for the site-visit.

6.2.1.2 In preparation for the site-visit, where possible and available, the investigator requests from the PIC, pharmacy owner or their representative (through the PBC or Sales Point of Contact, or other Cardinal Health employees where necessary)

data that assists in the evaluation of the customer.

6.2.1.3 The investigator reviews customer information. Depending on the circumstances of the investigation and the customer this may include, but is not limited to, information located in the following systems:

a. SOM / ADC system information
b. Data supplied by the QRA Analytics Team such as Tableau Reports generated from customer purchase history
c. Information supplied by the requester of the site-visit, included in the ADC site-visit request
d. Distrack or other relevant source

6.2.1.4 The investigator performs an internet search query including, but not limited to:

a. Google
b. Address and phone
c. Location photographs from Google Earth or Yahoo Maps
d. DEA # verification
e. Secretary of State (Corporate information)
f. Department of Health and State Board of Pharmacy
g. Other relevant sources

6.2.1.5 The investigator documents in the investigation report ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"]) if any research reveals items that require additional attention. The investigator advises the Director of these items and have copies available if necessary.

6.2.2 Site-Visit

6.2.2.1 The investigator conducts the investigation according to this SOP using the training provided by Cardinal Health management as well as their own knowledge and experience. All investigations must be documented on [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"].

6.2.2.2 The investigator collects and documents information from the customer that is relevant to the investigation, including dispensing and prescription data.

6.2.2.3 The investigator, following the site-visit report template, asks questions related to the data and other information provided by the customer. The Investigator must ask questions about those efforts that the customer has in place to ensure controlled substance prescriptions are being filled for legitimate medical purposes, including questions about understanding and application of corresponding responsibility and due diligence measures.

6.2.2.4 The investigator observes the pharmacy and documents any visible signs of diversion including:

a. Long lines outside the pharmacy.

b. Patients and customers at the pharmacy not congruent with the demographics and economics of the area.
c. Disproportional out-of-state vehicles parked outside the pharmacy.
d. Any evidence of illicit drug use around the pharmacy.
e. Presence of any mailing materials or any other evidence of an internet pharmacy.
f. Any other obvious signs of diversion at the pharmacy.

6.2.3 Completing Site-Visit Report Sections

6.2.3.1 The investigator obtains prescription information by completing questions on:

a. Average number of total prescriptions per day
b. Average number of total prescriptions paid in cash per day
c. Average number of controlled substance prescriptions per day
d. Average number of controlled substance prescriptions paid in cash per day
e. Dispensing of highly diverted strengths of Oxycodone, Hydrocodone, Alprazolam and all other controlled substances of interest

6.2.3.2 The actual numbers must be obtained from the customer. If the actual numbers are unavailable, the investigator requests the pharmacist to provide an estimate.

6.2.3.2.1 Explanations must be sought if the percentage of controlled substance prescriptions paid for in cash is significantly higher than benchmarks.

6.2.3.2.2 Explanations must also be sought if the percentage of controlled substance prescriptions paid in cash is significantly higher (**e.g.**, larger than 4%) than that of the non-controlled substances paid for in cash.

6.2.3.2.3 Explanations must also be sought if a high level dispensing of most likely diverted strengths is observed.

6.2.3.3 The investigator must complete the dispensing analysis section of the report. If this data is not readily available, Cardinal Health sales data is used. The investigator completes this section only for those controlled substance drug products that are of interest to Cardinal Health at this pharmacy – drugs of interest include drug families (among the 13 most likely diverted drug families) that were flagged as part of the suspicious order reporting process, LV-TAC review process or any from any other QRA processes or sources.

6.2.3.4 Based on Cardinal Health sales data in Tableau or other information supplied by the QRA Analytics Team the investigator must review if any of the drug families of interest experience disproportionate growth in the past twelve (12) months and investigate the reasons why.

6.2.3.5 The investigator must ask questions about the customer's business model and geographical area to assist with Cardinal Health efforts to continue to know the customer.

6.2.3.6 The investigator must include in the report any relevant and objective fact based comments that may assist the corporate reviewer in evaluating the customer.

6.2.4 Reviewer Assessment

6.2.4.1 Upon completion and submission of the final report the investigator submits the report to the director for review. The Director reviews the results of the investigation and must complete the corporate review section of the report based on the information provided therein. All reports are promptly uploaded to ADC for further review by the site-visit requestor and/or LV-TAC and/or other QRA team members. The investigator may be consulted on an ongoing basis after the report is completed.

6.2.5 Suspensions

6.2.5.1 If it is determined, based on the results of the investigation, that there is a significant risk of potential diversion, the Director suspends the customer from the ability to purchase controlled substances:

6.2.5.1.1 The Director completes the Reviewer Assessment portion of the report and indicate that the customer is suspended from the ability to purchase controlled substances and include the reason(s) why.

6.2.5.1.2 The QRA Account setup team promptly notifies Sales and the customer of the decision to suspend the sales of controlled substances.

6.2.5.1.3 The Director promptly “block” or restrict the customer from purchasing controlled substances via ADC. The Director also “blocks” or restrict the customer from purchasing monitored but not-non-controlled products via Distract (for drug family numbers 2166, 5001, 7100).

6.2.5.1.4 The Director records a comment in ADC that references the suspension and the report.

6.2.5.1.5 The Director sends an email to the appropriate QRA, Operations, Sales and other appropriate Cardinal Health personnel about the suspension.

6.2.5.2 For any other type of customer suspension (**e.g.**, LV-TAC review, QRA R.Ph review, etc.) that occurs after the final report has been uploaded to ADC, the Director must be notified. A Decision Memo ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form3.docx"]) that documents the decision to suspend and the reason why must be completed. The Directorl uploads the memo to ADC and records a comment in ADC that references the suspension and the memo. The Director also follows §6.2.5.1.2-§6.2.5.1.5 listed above.

6.2.5.3 In the event that Cardinal Health receives written notification from a supplier that a Cardinal Health customer is being denied chargebacks by the supplier for certain controlled substances, the customer is suspended as defined in

§6.2.5.1.2-§6.2.5.1.5 listed above. The investigations team maintains a record of all letters received from suppliers, including restriction and reinstatement letters.

6.3 Reinstatements

6.3.1.1 Any customer that has been suspended from purchasing controlled and monitored substances may apply for reinstatement with Cardinal Health after a reasonable amount of time from the date they were suspended.

6.3.1.2 All requests for reinstatement must come through the QRA Account Setup team, who requests an on-site-visit by a QRA investigator via ADC.

6.3.1.3 The completed site-visit report ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"]) must be reviewed by the Director and the QRA Account Setup Director to determine if the reasons that led to the suspension have been mitigated. The Director uploads the completed report to ADC.

6.3.1.4 All reasonable requests for reinstatement must be submitted to and approved and documented by LV-TAC. The QRA Account Setup Team communicates all decisions regarding reinstatement to the customer.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Comments and statements must be based on factual data, site-visit observations and objective analysis of data gathered prior to and during site-visits.

7.1.2 Where the investigator has an opportunity to share with a customer QRA best practices for DEA registered pharmacists, the investigator may do so.

7.1.3 All documentation as required by this SOP must be filled out according to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/DR-P007.docx"].

7.2 Documentation Retention

7.2.1 All final documents must be promptly uploaded to ADC. within a reasonable period of time and retained for (3) three years or the most recent report if it is outside of three years. Documents in ADC uploaded by the investigations team consists of the following file code identifiers:

a. 110 – On-Site QRA Investigations
b. 102 – Surveillance site-visits
c. 062 - Call Surveys
d. 060 – Decision Memos.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

QRA INVESTIGATIONS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Todd Cameron				Owner: Ullrich Mayeski PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3304	26 Apr 2013	Modify	Yes	Corporate	PDQRA - Investigations
Other (specify)					
N/A					
Change Description and Justification					
Updated to conform with current Cardinal Health practices. Updated document owner to Ullrich Mayeski. Updated document approver to Todd Cameron.					

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

NATIONAL ACCOUNT TYPES THAT BYPASS CORPORATE QUALITY AND REGULATORY AFFAIRS DUE DILIGENCE

1.0 PURPOSE

To define the types of National Accounts that bypass the Corporate Quality and Regulatory Affairs (QRA) Anti-Diversion due diligence review process.

2.0 SCOPE

This Standard Operating Procedure (SOP) applies to National Accounts / Chains within Pharmaceutical Distribution and other businesses as adopted.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK \l "_Attachment_1"]{ ~~HYPERLINK \l "_Attachment_1"~~ }	Accounting Class Codes
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/Forms/DispForm.aspx?ID=955"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/Forms/DispForm.aspx?ID=955"~~ }	National Account / Chain Customer Know Your Customer Due Diligence Process

4.0 RESPONSIBILITIES

The National Account Team, the Corporate QRA Anti-Diversion New Account Set-up (NAS) team, and the Customer Data Management & Compliance (CDMC) team, have responsibility for compliance to this SOP.

5.0 DEFINITIONS

Accounting Class Code (ACC) — A unique numeric identifier assigned to accounting classes.

Diversion — Diversion is defined in multiple ways:

- Product diversion
  - Excessive purchases of controlled substances with intent to sell or use illicitly.
  - Introduction into the market of pharmaceuticals that are counterfeit, adulterated, misbranded, improperly stored or shipped, or otherwise unreliable.
  - Improper sales into the secondary market.
  - Improper internet sales.

- Theft

- Price diversion
  - Any use or sale of a pharmaceutical product by a closed-door or retail pharmacy that violates "own use".

Due Diligence File — A collection of relevant, customer-specific documents maintained as part of the Anti-Diversion Suspicious Order Monitoring program. These documents are identified in PDQRA-CAD-C010, Attachment 1.

New Account Set-up (NAS) SharePoint Site — The NAS SharePoint site is a centralized collection of pages, site templates, lists, and libraries configured to drive behavior for Pharmaceutical Distribution (PD) NAS, Maintenance, and Technology requests. The NAS site uses a parallel workflow that allows the requests to route to multiple PD approval groups for review at the same time.

6.0 PROCEDURE

6.1 Due Diligence Review

6.1.1 Prior to the initial sale of controlled substance products, the National Account team conducts a due diligence review of the proposed customer. If the customer, at the conclusion of the process, is determined to pose an unreasonable risk for diversion, controlled substance products are not sold to the customer.

6.1.2 New National Accounts, as determined as such by the National Account team, bypass Corporate QRA Anti-Diversion NAS in the new account SharePoint workflow approval process. A due diligence review is completed for these National Accounts by the National Account team.

6.1.2.1 New National Accounts bypass Corporate QRA Anti-Diversion in the SharePoint workflow by either having a certain Accounting Class Code (see [HYPERLINK \l " _Attachment_1"]{ HYPERLINK \l "_Attachment_1" }), or by a "Yes" answer to the following question on the new account setup form, "Is this a National Account Alternate Care or Mail Order customer?"

6.1.2.1.1 The National Account Team is the only team that is authorized to answer this question "Yes". The CDMC team only accepts new account setup requests where this question has been answered "Yes" from the approved list of National Account Team members. The National Account Team Supervisor must maintain this list and provide it to the CDMC team as needed.

6.1.2.2 National Accounts typically consist of, but are not limited to, National Chain Pharmacies, National Alternate Care Accounts, National Mail Order Accounts, National Warehouse Accounts, and Government Accounts, and typically fall within, but are not limited to, the Accounting Class Codes found in [HYPERLINK \l " Attachment_1"]{ HYPERLINK \l "_Attachment_1" }.

6.1.2.3 Any National Account requests that flow through the Corporate QRA Maintenance queue, or the Corporate QRA Customer Number License Versioning (CNLV) queue, are automatically approved by Corporate QRA with no action taken by Corporate QRA from a due diligence standpoint as these requests must have a due diligence review performed by the National Accounts team according to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/Forms/DispForm.aspx?ID=955"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/Forms/DispForm.aspx?ID=955" ~~}.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Not applicable.

7.2 Documentation Retention

7.2.1 Not applicable.

NATIONAL ACCOUNT TYPES THAT BYPASS CORPORATE QUALITY AND REGULATORY AFFAIRS DUE DILIGENCE

Attachment 1

ACCOUNTING CLASS CODES	
20	CHAIN PHARMACY
21	CHAIN SUPERMARKET
22	CHAIN MASS MERCHANDISER
23	CHAIN MAIL ORDER
24	CHAIN WAREHOUSE
40	NATIONAL MANAGED CARE/HMO/PPO
41	NATIONAL MANAGED CARE HOME INFUSION
42	NATIONAL MANAGED CARE NURSING HOME
43	NATIONAL MANAGED CARE OTHER
44	NATIONAL MANAGED CARE MAIL ORDER
45	NATIONAL MANAGED CARE WAREHOUSE
60	GOVERNMENT FEDERAL
61	GOVERNMENT STATE

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

NATIONAL ACCOUNT TYPES THAT BYPASS CORPORATE QUALITY AND REGULATORY AFFAIRS DUE DILIGENCE

APPROVALS	
Approvals on file in the Pharmaceutical Distribution Corporate Document Center (PDCDC) Approver(s): Todd Cameron	Owner: Patrick Dudley PDCDC: [HYPERLINK "mailto:GMB-PD-QRA-Doc-Center@cardinalhealth.com"]{ HYPERLINK "mailto:GMB-PD-QRA-Doc-Center@cardinalhealth.com" }

CHANGE HISTORY

DCN	Effective Date	Change Type	Document Applicability	Implementation Timeframe (default 30 days)
4182	20 Jul 2015	New	Corporate	30 days
Change Description and Justification:				
Initial release of new SOP, PDQRA-CAD-C031, to define the types of National Accounts that bypasses the Corporate QRA Anti-Diversion due diligence review process.				

OTHER REFERENCES

Does this SOP apply to a WBT Module?	No
If yes - Does the WBT Module need to be modified due to changes made to this version?	N/A
If yes – Specify which WBT Module is affected.	N/A
Is this SOP referenced in the Self-Assessment website?	No
If yes - Does the Self-Assessment website need to be modified due to changes made to this version?	N/A

TRAINING

Training Required	Training Assignment(s)	Other (specify)
Yes	PDQRA - CDMC PDQRA - National Accounts PDQRA - New Accounts	N/A

If Cage / Vault Employees are trained, is On the Job Training (OJT) retraining required? (reference PDQRA-TP-P001 §6.5.1.5)	N/A
Training Highlights	N/A

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

NATIONAL ACCOUNT / CHAIN CUSTOMER KNOW YOUR CUSTOMER DUE DILIGENCE PROCESS

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to outline the process for the completion and the storing of the National Account / Chain Know Your Customer (KYC) questionnaire.

2.0 SCOPE

This SOP applies to National Account / Chains within Pharmaceutical Distribution and other businesses as adopted.

3.0 REFERENCES / RELATED DOCUMENTS

None

4.0 RESPONSIBILITIES

The National Account team is responsible for the completion of the National Account / Chain KYC. The Corporate Quality and Regulatory Affairs (QRA) Anti-Diversion New Account Set-up (NAS) team is responsible for reviewing any National Account / Chain KYCs that are considered an exception and requires Corporate QRA approval (see §6.1.5).

5.0 DEFINITIONS

Content Manager — Centralized document retention system used for customer specific documents.

Diversion — Diversion is defined in multiple ways:

- Product diversion
  - Excessive purchases of controlled substances with intent to sell or use illicitly.
  - Introduction into the market of pharmaceuticals that are counterfeit, adulterated, misbranded, improperly stored or shipped, or otherwise unreliable.
  - Improper sales into the secondary market.
  - Improper internet sales.
  - Theft
- Price diversion

Any use or sale of a pharmaceutical product by a closed-door or retail pharmacy that violates “own use”.

Know Your Customer (KYC) Questionnaire — Survey used to collect information about customers. The survey contains, among other items, questions specific to the customer’s business model and controlled substance needs.

Supply Chain Integrity SharePoint Repository — Database containing a collection of shared documents obtainable by permission rights.

NATIONAL ACCOUNT / CHAIN CUSTOMER KNOW YOUR CUSTOMER DUE DILIGENCE PROCESS

6.0 PROCEDURE

6.1 National Account / Chain KYC Process

6.1.1 Any National Account / Chain entity that has less than 100 DEA Registrants that make up the organization requires the completion of a National Account / Chain KYC questionnaire on behalf of each individual Drug Enforcement Administration (DEA) Registrant. Each KYC must be stored in Content Manager.

6.1.2 Any National Account / Chain entity that has 100 or more DEA Registrants that make up the organization requires the completion of one (1) Master National Account / Chain KYC questionnaire completed on behalf of the organization as a whole. The Master KYC must be stored in the Supply Chain Integrity SharePoint Repository.

6.1.3 If at any point the National Account / Chain entity that starts with less than 100 DEA Registrants grows to 100 or more DEA Registrants, the National Account team only needs to complete one (1) additional Master National Account / Chain KYC questionnaire on behalf of the organization as a whole. The Master must be stored in the Supply Chain Integrity SharePoint Repository.

6.1.3.1 In this situation, all previous KYC questionnaires for a National Account / Chain entity that previously had less than 100 DEA Registrants must be retained and stored in Content Manager.

6.1.4 The National Account team is responsible for the completion of the National Account / Chain KYC either on behalf of the customer or in conjunction with the customer. This includes the completion of the KYC questionnaire and the gathering of all required documentation including, but not limited to, state and federal licensure.

6.1.5 Any National Account / Chain KYC questionnaire that is an exception must be emailed, along with all supporting documentation, to the Director of Corporate QRA Anti-Diversion New Account Set-up for further review. A National Account / Chain KYC questionnaire is considered an exception if any of the following criteria exists:

6.1.5.1 A KYC questionnaire with a "YES" answer to any of the following questions is considered an exception and requires further review by Corporate QRA:

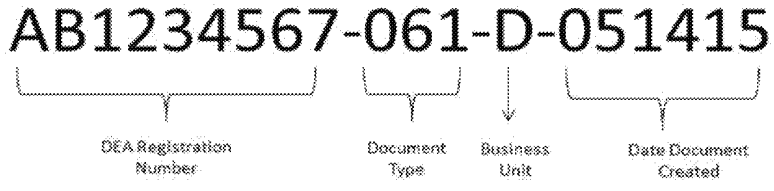
a. Are any of the Principle Owner's or Corporate Entity's current DEA registrations suspended or revoked?
b. Is there a record available of the Principle Owner or Corporate Entity being convicted of a crime relating to distribution of prescription drugs, or listed chemicals?
c. Is the DEA registration(s) of any of the National Account / Chain Pharmacy's entity suspended or revoked?

d. Has Cardinal Health been notified that other wholesalers ceased shipping or restricted purchases of controlled substances to any of these pharmacies because of a concern of diversion?
e. Did the Google Web Search result in any details supporting adverse or criminal activity involving the account, any details indicating the diversion of controlled substances occurred, or any details supporting the suspension or revocation of the pharmacy licenses or any individual licensees?

6.1.5.2 A KYC questionnaire completed as a master KYC survey for a National Account / Chain entity with 100 or more DEA Registrants regardless of any "YES/NO" answers within the document is also considered an exception and requires further review by Corporate QRA.

6.1.6 Once the KYC questionnaire is complete and all documentation has been gathered, the information must be converted into PDF format and saved.

6.1.6.1 When completed, the document must follow the below naming convention format:



6.1.7 The National Account team uploads the completed KYC questionnaires to Content Manager by placing them in the auto-upload folder designated for use.

6.1.8 On a quarterly basis the Corporate QRA Anti-Diversion Investigative team audits 15% of completed National Account / Chain KYCs.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Not applicable.

7.2 Documentation Retention

7.2.1 Not applicable.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

NATIONAL ACCOUNT / CHAIN CUSTOMER KNOW YOUR CUSTOMER DUE DILIGENCE PROCESS

APPROVALS	
Approvals on file in the Pharmaceutical Distribution Corporate Document Center (PDCDC) Approver(s): Todd Cameron	Owner: Patrick Dudley PDCDC: [HYPERLINK "mailto:GMB-PD-QRA-Doc-Center@cardinalhealth.com"]{ HYPERLINK "mailto:GMB-PD-QRA-Doc-Center@cardinalhealth.com" }

CHANGE HISTORY

DCN	Effective Date	Change Type	Document Applicability	Implementation Timeframe (default 30 days)
4261	20 Jul 2015	New	Corporate	30 days
Change Description and Justification:				
Initial release of new SOP, PDQRA-CAD-C032, to outline the process for the completion and the storing of the National Account / Chain KYC questionnaire.				

OTHER REFERENCES

Does this SOP apply to a WBT Module?	N/A
If yes - Does the WBT Module need to be modified due to changes made to this version?	N/A
If yes – Specify which WBT Module is affected.	N/A
Is this SOP referenced in the Self-Assessment website?	N/A
If yes - Does the Self-Assessment website need to be modified due to changes made to this version?	N/A

TRAINING

Training Required	Training Assignment(s)	Other (specify)
Yes	PDQRA - National Accounts PDQRA - New Accounts	N/A
If Cage / Vault Employees are trained, is On the Job Training (OJT) retraining required? (reference PDQRA-TP-P001 §6.5.1.5)		N/A
Training Highlights	N/A	

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

NATIONAL ACCOUNT / CHAIN CUSTOMER DUE DILIGENCE PROCESS

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to outline the process for the completion and the storing of the National Account / Chain due diligence packet.

2.0 SCOPE

This SOP applies to National Account / Chains within Pharmaceutical Distribution and other businesses as adopted.

3.0 REFERENCES / RELATED DOCUMENTS

None

4.0 RESPONSIBILITIES

The National Account team is responsible for the completion of the National Account / Chain due diligence packet. The Corporate Quality and Regulatory Affairs (QRA) Anti-Diversion New Account Set-up (NAS) team is responsible for reviewing any National Account / Chain due diligence packets that are considered an exception and require Corporate QRA approval (see §6.1.5).

5.0 DEFINITIONS

Content Manager — Centralized document retention system used for customer specific documents.

Diversion — Diversion is defined in multiple ways:

- Product diversion
  - Excessive purchases of controlled substances with intent to sell or use illicitly.
  - Introduction into the market of pharmaceuticals that are counterfeit, adulterated, misbranded, improperly stored or shipped, or otherwise unreliable.
  - Improper sales into the secondary market.
  - Improper internet sales.
  - Theft
- Price diversion

Any use or sale of a pharmaceutical product by a closed-door or retail pharmacy that violates “own use”.

Know Your Customer (KYC) Questionnaire — Survey used to collect information about customers. The survey contains, among other items, questions specific to the customer’s business model and controlled substance needs.

Specialty Pharmaceutical Services (SPS) SharePoint — Database containing a collection of shared documents obtainable by permission rights.

Repository

6.0 PROCEDURE

6.1 National Account / Chain Due Diligence Process

6.1.1 Any National Account / Chain entity that has less than 100 DEA Registrants that make up the organization requires the completion of a National Account / Chain due diligence packet on behalf of each individual Drug Enforcement Administration (DEA) Registrant. Each due diligence packet must be stored in Content Manager.

6.1.2 Any National Account / Chain entity that has 100 or more DEA Registrants that make up the organization requires the completion of one (1) Master National Account / Chain due diligence packet completed on behalf of the organization as a whole. The Master due diligence packet must be stored in the SPS SharePoint Repository.

6.1.3 If at any point the National Account / Chain entity that starts with less than 100 DEA Registrants grows to 100 or more DEA Registrants, the National Account team only needs to complete one (1) additional Master National Account / Chain due diligence packet on behalf of the organization as a whole. The Master due diligence packet must be stored in the SPS SharePoint Repository.

6.1.3.1 In this situation, all previous due diligence packets for a National Account / Chain entity that previously had less than 100 DEA Registrants must be retained and stored in Content Manager.

6.1.4 The National Account team is responsible for the completion of the National Account / Chain due diligence packet either on behalf of the customer or in conjunction with the customer. This includes the completion of the KYC questionnaire and the gathering of all required documentation including, but not limited to, state and federal licensure.

6.1.5 Any National Account / Chain KYC questionnaire that is an exception must be emailed, along with all supporting documentation, to the Director of Corporate QRA Anti-Diversion New Account Set-up for further review. A National Account / Chain KYC questionnaire is considered an exception if any of the following criteria exists:

6.1.5.1 A KYC questionnaire with a "YES" answer to any of the following questions is considered an exception and requires further review by Corporate QRA:

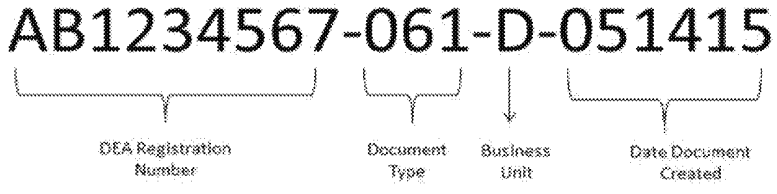
a. Are any of the Principle Owner's or Corporate Entity's current DEA registrations suspended or revoked?
b. Is there a record available of the Principle Owner or Corporate Entity being convicted of a crime relating to distribution of prescription drugs, or listed chemicals?

c. Is the DEA registration(s) of any of the National Account / Chain Pharmacy's entity suspended or revoked?
d. Has Cardinal Health been notified that other wholesalers ceased shipping or restricted purchases of controlled substances to any of these pharmacies because of a concern of diversion?
e. Did the Google Web Search result in any details supporting adverse or criminal activity involving the account, any details indicating the diversion of controlled substances occurred, or any details supporting the suspension or revocation of the pharmacy licenses or any individual licensees?

6.1.5.2 A due diligence packet completed as a Master due diligence packet for a National Account / Chain entity with 100 or more DEA Registrants regardless of any "YES/NO" answers within the KYC document is also considered an exception and requires further review by Corporate QRA.

6.1.6 Once the due diligence packet is complete and all documentation has been gathered, the information must be converted into PDF format and saved.

6.1.6.1 When completed, the document must follow the below naming convention format:



6.1.7 The National Account team uploads the completed due diligence packet to Content Manager by placing them in the auto-upload folder designated for use.

6.1.8 On a quarterly basis the Corporate QRA Anti-Diversion Investigative team audits 15% of completed National Account / Chain due diligence packets.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Not applicable.

7.2 Documentation Retention

7.2.1 Not applicable.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

NATIONAL ACCOUNT / CHAIN CUSTOMER DUE DILIGENCE PROCESS

APPROVALS	
Approvals on file in the Pharmaceutical Distribution Corporate Document Center (PDCDC) Approver(s): Todd Cameron	Owner: Patrick Dudley PDCDC: [HYPERLINK "mailto:GMB-PD-QRA-Doc-Center@cardinalhealth.com"]{ HYPERLINK "mailto:GMB-PD-QRA-Doc-Center@cardinalhealth.com" }

CHANGE HISTORY				
DCN	Effective Date	Change Type	Document Applicability	Implementation Timeframe (default 30 days)
4407	26 Oct 2015	Modified	Corporate	30 days
Change Description and Justification:				
Changed Supply Chain Integrity SharePoint definition to SPS SharePoint in §5.0 to align with process. Changed §6.1.2 from Supply Chain Integrity SharePoint to SPS SharePoint to align with process. Changed references from Know Your Customer to due diligence process to eliminate confusion between the two.				

OTHER REFERENCES		
Does this SOP apply to a WBT Module?		N/A
If yes - Does the WBT Module need to be modified due to changes made to this version?		N/A
If yes - Specify which WBT Module is affected.	N/A	
Is this SOP referenced in the Self-Assessment website?		N/A
If yes - Does the Self-Assessment website need to be modified due to changes made to this version?		N/A

TRAINING		
Training Required	Training Assignment(s)	Other (specify)
No	PDQRA - National Accounts PDQRA - New Accounts	N/A
If Cage / Vault Employees are trained, is On the Job Training (OJT) retraining required? (reference PDQRA-TP-P001 §6.5.1.5)		N/A
Training Highlights	N/A	

Ending and Single Digit Threshold Limit Guidelines
General Work Instructions

Scope

The general guidelines apply to all individuals who have the ability and/or direct responsibility for assessing and adjusting customer specific threshold limits within the electronic monitoring system of Cardinal Health's Suspicious Order Monitoring (SOM) program.

Statement

Cardinal Health's Anti-Diversion department will have a standardized method to adjust threshold limits utilized within the electronic monitoring system of the Suspicious Order Monitoring (SOM) program. This provides guidance on the specific ending digit that can, in certain scenarios be applied when making adjustments to threshold limits. The following ending digits are to be applied when making threshold limit adjustments in the following scenarios.

Ending Digit	Initiated By	Definition
2	Advanced Analytics	Indicates a secondary account for customers that have both PD and Kinray accounts.
3	Advanced Analytics	Indicates a static threshold limit to accommodate the number of days in a month and statistically identified higher prescribing days affecting a customers purchase pattern.
4	SPS	Identifies customer as SPS.
5	Pharmacists / Customer Analytics / NAS	Indicates designated reviewed and approved threshold limit adjustment(s), which warrant continued review.
7	Customer Analytics	Identifies customer as being in a Tertiary wholesale position.
8	Customer Analytics	Indicates a settlement agreement is in place between Cardinal Health and the pharmacy under which notice may be required prior to an adjustment to threshold limit.
9	LV-TAC	Indicates decisions recommended and agreed upon by LV-TAC (Large Volume-Tactical Analytical Committee).
11	Advanced Analytics	Indicates 107/118 drug families in our system that SPD currently does not carry.
32/72	Advanced Analytics	Indicates customer has accounts in both PD and Kinray where they have chosen to have their threshold limits split into 30% for one DC and 70% for the other.

Single Digit	Initiated By	Definition
2	Advanced Analytics	Indicates customer has threshold limits in our system, but their accounts are inactive at the DC.

When making subsequent changes to threshold limits with a designated ending digit, the following processes are to be followed:

- Any increase to a threshold limit for Hydrocodone and Oxycodone drug families above 20,010 needs two-person concurrence; any increase to a threshold limit for Hydrocodone and Oxycodone drug families above 39,999 needs to be approved by Vice President of Supply Chain Integrity, or designee. Any change to any other drug family above the corresponding second level review quantity requires two-person concurrence.[1]
- Any proposed change to a threshold limit ending in 5 or 8 needs to be reviewed in conjunction with the originator of the ending digit. If agreement is reached that change is appropriate, and the increase is to a threshold limit less than 20,010, then the threshold limit may be changed. Proposed

[1] Please refer to: "Two-Person Approval Support Guidelines and Documentation" for guidance.

increases above 20,010 under the aforementioned scenario require two-person concurrence at a Director level or above.

Objective Criteria Application Guidance

This is a standalone document independent of DMQ, used to aid in the consistent application of objective criteria, although can certainly be used as support in the review of a pharmacy under DMQ.

The application of objective criteria should always be used in instances where requests are made for threshold review, focusing on the pieces of objective criteria relevant to the request. If there is a DMQ held order, and based on all available information at the time of review, makes sense to request dispensing and specialty information (as though you would in the case of sales generating a threshold review request), go ahead and do so.

With regard to information requests, there may be instances where based on all available information at the time and based on our lower risk levels, it may not be necessary to request dispensing and other information for review. Some examples may include, but are not limited to, pharmacies whose threshold limits are appropriately set at 6,000 oxycodone and 6,000 hydrocodone, pharmacies whose threshold limits are set at the 3S template, or pharmacies whose threshold limits appear to be set appropriately based on purchase history. The objective criteria should be used as a guide, to support conversations regarding threshold limit adjustments, whether up or down.

At any point a threshold review is requested or when appropriate, if any of the conditions below are exceeded for any drug family/class that the reviewer has not recently reached out for/received updated dispensing/specialty information, the reviewer should request information for threshold review (if appropriate based on the below logic) which may result in threshold adjustments, further review by senior leadership/LV-TAC or no change.

Overview:

Objective Criteria	Percentile	Dosage Unit of Specific OC
Oxycodone 15/30MG	≥ 80th	≥ 8,000
Hydrocodone 10MG	≥ 80th	≥ 15,000
Alprazolam 2MG	≥ 80th	≥ 5,000
% Controlled Substances	≥ 80th	≥ 50,000
% OH Scripts	≥ 80th	See below chart
% ADHD	≥ 80th	≥ 10,000
% Benzos	≥ 80th	≥ 20,000
% Opioids	≥ 80th	≥ 30,000

Rx/Mo	Percentile	Dosage Units of OH
0 - 2,778	≥ 80th	≥ 20,000
2,779 - 5,000	≥ 80th	≥ 30,000
5,001 +	≥ 80th	≥ 40,000

Oxycodone 15/30MG Review:

If the percentage of oxycodone that is oxycodone 15/30MG product sets them ≥ the 80th percentile and ≥ 8,000 dosage.

Objective Criteria	Percentile	Dosage Unit of Specific OC
Oxycodone 15/30MG	≥ 80th	≥ 8,000

Hydrocodone 10MG Step Review:

If the percentage of hydrocodone that is hydrocodone 10MG product sets them ≥ the 80th percentile and ≥ 15,000 dosage units AND in conjunction with ANY of the following:

- The percentage of all prescriptions (outlined below) that is oxycodone and hydrocodone prescriptions sets them ≥ the 80th percentile and ≥ the respective dosage units below.
- The percentage of all prescription drug dosage units dispensed that is an opioid sets them ≥ the 80th percentile and ≥ 30,000 dosage units.
- The percentage of prescription drug dosage units that is controlled substances is ≥ the 80th percentile and ≥ 50,000 dosage units.

Objective Criteria	Percentile	Dosage Unit of Specific OC
Hydrocodone 10MG	≥ 80th	≥ 15,000
In conjunction with <u>any</u> of the below:		
% OH Scripts	≥ 80th	See below table
% Opioids	≥ 80th	≥ 30,000
% Controlled Substances	≥ 80th	≥ 50,000

Rx/Mo	Percentile	Dosage Units of OH
0 - 2,778	≥ 80th	≥ 20,000
2,779 - 5,000	≥ 80th	≥ 30,000
5,001 +	≥ 80th	≥ 40,000

Alprazolam 2MG Step Review:

If the percentage of alprazolam that is alprazolam 2MG product sets them ≥ the 80th percentile and ≥ 5,000 dosage units AND in conjunction with ANY of the following:

- The percentage of controlled substance units dispensed that is a benzodiazepine is ≥ the 80th percentile and ≥ 20,000 dosage units.
- The percentage of prescription drug dosage units that is controlled substances is ≥ the 80th percentile and ≥ 50,000 dosage units.

Objective Criteria	Percentile	Dosage Unit of Specific OC
Alprazolam 2MG	≥ 80th	≥ 5,000
In conjunction with either of the below:		
% Benzos	≥ 80th	≥ 20,000
% Controlled Substances	≥ 80th	≥ 50,000

Any ADHD:

If the percentage of controlled substance units dispensed that is an ADD/ADHD sets them ≥ the 80th percentile and ≥ 10,000 dosage units AND in conjunction with the following:

- The percentage of prescription drug dosage units that is controlled substances is ≥ the 80th percentile and ≥ 50,000 dosage units.

Objective Criteria	Percentile	Dosage Unit of Specific OC
% ADHD	≥ 80th	≥ 10,000
In conjunction with the below:		
% Controlled Substances	≥ 80th	≥ 50,000

*See drug class appendix below

Any Benzo:

If the percentage of controlled substance units dispensed that is a benzodiazepine sets them ≥ the 80th percentile and ≥ 20,000 dosage units AND in conjunction with the following:

- The percentage of prescription drug dosage units that is controlled substances is ≥ the 80th percentile and ≥ 50,000 dosage units.

Objective Criteria	Percentile	Dosage Unit of Specific OC
% Benzos	≥ 80th	≥ 20,000
In conjunction with the below:		
% Controlled Substances	≥ 80th	≥ 50,000

*See drug class appendix below

Any Opioid:

If the percentage of all prescription drug dosage units dispensed that is an opioid sets them ≥ the 80th percentile and ≥ 30,000 dosage units AND in conjunction with the following:

- The percentage of prescription drug dosage units that is controlled substances is ≥ the 80th percentile and ≥ 50,000 dosage units.

Objective Criteria	Percentile	Dosage Unit of Specific OC
% Opioid	≥ 80th	≥ 30,000
In conjunction with the below:		
% Controlled Substances	≥80th	≥ 50,000

*See drug class appendix below

WW

- Will changes be made to the Regulatory Tab on the Customer 360 page in WinWatcher?
  - Yes! The score/total score in WW will be replaced with the pharmacy's percentile/total percentile, everything else remaining the same.
- Will the threshold-setting methodology change with the update in Objective Criteria.
  - No, the threshold-setting methodology will not change.
- Will the sales team need to gather/supply information differently to the Anti-Diversion team for threshold limit reviews?
  - No, the same questionnaire templates will be utilized to collect additional information for the review of a drug family threshold limit.

Threshold Limit Adjustment Language

If additional information is supplied that the reviewer feels warrants an adjustment to the threshold limit, please select the appropriate drug family in ADC, and include the below language and any additional relevant detail to support the adjustment such as nearby store closure/file absorption or contract with a new hospice facility.

- Threshold limit adjusted to align with ____ rx/mo. and update dispensing of ___ dosage units/mo. Drug family and zone (if applicable) and if the adjustment is to either oxycodone or hydrocodone include the combined threshold limit percent.

ISF Portal Documents

- The finalized documents will be routed up through legal prior to deployment mid-May.

Base Code	Drug Family Name	Class
1100	DL-AMPHETAMINE SULFATE MONOBASIC	ADHD
1105	D-METHAMPHETAMINE HYDROCHLORIDE	ADHD
1205	LISDEXAMFETAMINE MESYLATE	ADHD
1724	METHYLPHENIDATE HYDROCHLORIDE	ADHD
6699	IODINE [LIST 1 CHEMICAL]	MONITORED
7100	PROPOFOL	MONITORED
8112	PSEUDOEPHEDRINE [LIST 1 CHEMICAL]	MONITORED
8113	EPHEDRINE [LIST 1 CHEMICAL]	MONITORED
2737	CLONAZEPAM	BENZOS
2751	CLOBAZAM	BENZOS
2756	ESTAZOLAM	BENZOS
2764	PRAZEPAM	BENZOS
2765	DIAZEPAM	BENZOS
2767	FLURAZEPAM	BENZOS
2768	CLORAZEPATE DIPOTASSIUM	BENZOS
2835	OXAZEPAM	BENZOS
2881	QUAZEPAM	BENZOS
2882	ALPRAZOLAM	BENZOS
2884	MIDAZOLAM HCL	BENZOS
2885	LORAZEPAM	BENZOS
2887	TRIAZOLAM	BENZOS
2925	TEMAZEPAM	BENZOS
9041	COCAINE,AMINO	OPIOID
9050	CODEINE PHOSPHATE	OPIOID
9064	BUPRENORPHINE HYDROCHLORIDE	OPIOID
9120	DIHYDROCODEINE BITARTRATE	OPIOID
9143	OXYCODONE HYDROCHLORIDE	OH
9150	HYDROMORPHONE HYDROCHLORIDE	OPIOID
9170	DIPHENOXYLATE HYDROCHLORIDE	OPIOID
9193	HYDROCODONE BITARTRATE	OH
9220	LEVORPHANOL TARTRATE	OPIOID
9230	MEPERIDINE HCL	OPIOID
9250	METHADONE HYDROCHLORIDE	OPIOID
9300	MORPHINE SULFATE	OPIOID
9630	TINCTURE OF OPIUM	OPIOID
9639	OPIUM	OPIOID
9652	OXYMORPHONE HYDROCHLORIDE	OPIOID
9655	PAREGORIC/OPIUM	OPIOID
9709	PENTAZOCINE HCL	OPIOID
9720	BUTORPHANOL	OPIOID
9737	ALFENTANIL HYDROCHLORIDE	OPIOID

9739	REMIFENTANIL HYDROCHLORIDE	OPIOID
9740	SUFENTANIL CITRATE	OPIOID
9780	TAPENTADOL HCL	OPIOID
9801	FENTANYL CITRATE	OPIOID